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**M143 M146 M148 M155 M159 M163**  
**U1S S1782 S1894 S1901**

(56) Documents Cited  
**EP 0234468 A2 WO95/03984 A1 WO 92/11190 A2**  
**WO 87/07625 A1 US 4902745 A US 4845145 A**  
**US 4664275 A**

(58) Field of Search  
UK CL (Edition O ) **C3M MD MXC , C3V VEK**  
INT CL<sup>6</sup> **B65D , C09K , F16J**  
Online: **WPI**

(54) Abstract Title  
**Sealing material for use in a valve for an aerosol inhaler**

(57) The present invention provides a seal for a valve for use in a pharmaceutical metered dose aerosol inhaler device, which seal is formed from a mixture comprising a cross-linked elastomeric material and one or both of a thermoplastic material and a thermoplastic elastomeric material.

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Sealing Material

5 The present invention relates to a sealing material and, in particular, to a sealing material for a valve for use in a pharmaceutical metered dose aerosol inhaler device.

10 Known rubber compounds for sealing pharmaceutical metered dose aerosol inhalers are based on the traditional technology of vulcanising a synthetic or natural rubber polymer. Such rubbers have chemical and physical properties conducive to good valve performance. Seal components have also been manufactured from thermoplastic or thermoplastic elastomer materials. Owing to their relative chemical  
15 inertness, these rubbers often have the advantage of low taste and odour. Furthermore, they are generally cheaper to convert into seals and have better quality extractive profiles than vulcanised rubbers.

20 The present inventor has now developed a mixture which results in an improved extract profile whilst still possessing the material properties necessary for good valve performance, such as chemical compatibility (swell), tensile strength, permanent compression set, stress relaxation and elastic modulus.

25 Accordingly, the present invention provides a seal for a valve for use in a pharmaceutical metered dose aerosol inhaler device, which seal is formed from a mixture comprising a cross-linked elastomeric material and one or both of a thermoplastic material and a thermoplastic elastomeric material (TPE).  
30

Advantageously the cross-linked elastomeric material is selected from one or more of the following: natural rubber, ethylene-propylene rubbers, such as ethylene-propylene-diene rubber,  
35 nitrile rubbers, such as butadiene-acrylonitrile

rubber, butadiene-styrene rubbers, butyl rubbers, chlorosulphonated polyethylene rubbers, fluorocarbon rubbers, polychloroprene rubbers, polysulphide rubbers, silicone rubbers, isoprene rubbers, isoprene-  
5 isobutene rubbers, polypropylene oxide rubbers and fluorosilicone rubbers. The cross-linked elastomeric material is preferably present in the mixture in an amount of from 50 to 97%.

Advantageously the thermoplastic material is  
10 selected from one or more of the following polymers: acrylonitrile-butadiene-styrene, acrylic, polyacetal homopolymers or copolymers, polyamides, such as nylon, polycarbonates, polyethylene, polypropylene, polystyrene, polysulphone, polytetrafluoroethylene,  
15 vinyl polymers, such as polyvinylchloride and polyvinyl acetate, polyethylene terephthalate, polybutylene terephthalate, cellulosic polymers, such as cellulose acetate and cellulose acetate butyrate and polybutylene. The thermoplastic material is  
20 preferably present in the mixture in an amount of from 3 to 50%.

Advantageously the thermoplastic elastomeric material is selected from one or more of the following: polyester rubbers, polyurethane rubbers,  
25 ethylene vinyl acetate rubber, styrene butadiene rubber, copolyether ester TPE, olefinic TPE, polyester amide TPE and polyether amide TPE. The thermoplastic elastomeric material is preferably present in the mixture in an amount of from 3 to 50%.

30 It will be appreciated that the seal may further comprise fillers, reinforcement agents, plasticisers, binders, stabilizers, lubricants and pigments to adjust the material properties and processability.

The present invention also provides a valve for  
35 use in a pharmaceutical metered dose aerosol inhaler

device having a seal as herein described.

The present invention still further provides a pharmaceutical metered dose aerosol inhaler device having a valve as herein described.

5           In another aspect of the present invention there is provided the use of a mixture comprising a cross-linked elastomeric material and one or both of a thermoplastic material and a thermoplastic elastomeric material for forming a seal for a valve for a  
10 pharmaceutical metered dose aerosol inhaler device.

          In yet another aspect of the present invention there is provided a method of making a seal for a valve for use in a pharmaceutical metered dose aerosol inhaler device, which method comprises the step of  
15 forming a mixture comprising a cross-linked elastomeric material and one or both of a thermoplastic material and a thermoplastic elastomeric material.

          It will be appreciated that the seal may be  
20 provided as a separate component or may be formed integrally with the valve.

          It has been found that the present invention provides particularly favourable results when used in conjunction with a hydrofluorocarbon propellant in the  
25 aerosol device.

          The seal of the present invention may be manufactured by any of the processes conventional in the art. For example, the seal may be manufactured by compression moulding, injection moulding or extrusion.

30           The advantages of the present invention include cost savings, greater control over component quality, reduced extractives, less reliance on externally sourced rubber goods and substantial elimination of an interface which reduces potential leakage paths.  
35

Claims:

5           1.    A seal for a valve for use in a  
pharmaceutical metered dose aerosol inhaler device,  
which seal is formed from a mixture comprising a  
cross-linked elastomeric material and one or both of a  
thermoplastic material and a thermoplastic elastomeric  
10       material.

          2.    A seal as claimed in claim 1, wherein the  
cross-linked elastomeric material is selected from one  
or more of the following: natural rubber, ethylene-  
15       propylene rubbers, such as ethylene-propylene-diene  
rubber, nitrile rubbers, such as butadiene-  
acrylonitrile rubber, butadiene-styrene rubbers, butyl  
rubbers, chlorosulphonated polyethylene rubbers,  
fluorocarbon rubbers, polychloroprene rubbers,  
20       polysulphide rubbers, silicone rubbers, isoprene  
rubbers, isoprene-isobutene rubbers, polypropylene  
oxide rubbers and fluorosilicone rubbers.

          3.    A seal as claimed in claim 1 or claim 2,  
25       wherein the thermoplastic material is selected from  
one or more of the following polymers: acrylonitrile-  
butadiene-styrene, acrylic, polyacetated homopolymers  
or copolymers, polyamides, such as nylon,  
polycarbonates, polyethylene, polypropylene,  
30       polystyrene, polysulphone, polytetrafluoroethylene,  
vinyl polymers, such as polyvinylchloride and  
polyvinyl acetate, polyethylene terephthalate,  
polybutylene terephthalate, cellulosic polymers, such  
as cellulose acetate and cellulose acetate butyrate  
35       and polybutylene.

4. A seal as claimed in any one of the preceding claims, wherein the thermoplastic elastomeric material is selected from one or more of the following: polyester rubbers, polyurethane  
5 rubbers, ethylene vinyl acetate rubber, styrene butadiene rubber, copolyether ester TPE, olefinic TPE, polyester amide TPE and polyether amide TPE.

5. A seal as claimed in any one of the preceding claims, further comprising one or more of  
10 the following: fillers, reinforcement agents, plasticizers, binders, stabilizers, lubricants and pigments.

6. A valve for use in a pharmaceutical metered dose aerosol inhaler device having a seal as claimed  
15 in any one of claims 1 to 5.

7. A pharmaceutical metered dose aerosol  
20 inhaler device having a valve as claimed in claim 6.

8. Use of a mixture comprising a cross-linked elastomeric material and one or both of a thermoplastic material and a thermoplastic elastomeric  
25 material for forming a seal for a valve for a pharmaceutical metered dose aerosol inhaler device.

9. A method of making a seal for a valve for use in a pharmaceutical metered dose aerosol inhaler  
30 device, which method comprises the step of forming a mixture comprising a cross-linked elastomeric material and one or both of a thermoplastic material and a thermoplastic elastomeric material.



Application No: GB 9706252.5  
Claims searched: 1-9

Examiner: K. Macdonald  
Date of search: 25 June 1997

**Patents Act 1977**  
**Search Report under Section 17**

**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:  
UK CI (Ed.O): C3M(MD,MXC); C3V(VEK)  
Int CI (Ed.6): C09K; F16J; B65D  
Other: Online: WPI

**Documents considered to be relevant:**

Category	Identity of document and relevant passage	Relevant to claims
X,Y	EP 0234468 A2 (DU PONT) see Claim 1; page 14, line 30	X:1,8 and 9 at least Y:6 and 7 at least
Y	WO 95/03984 A1 (MMM) see Claim 1	6 and 7 at least
Y	WO 92/11190 A2 (MMM) see Claims 41, 55	6 and 7 at least
X,Y	WO 87/07625 A1 (EXXON) see Claim 1; page 6, line 19	X:1,8 and 9 at least Y:6 and 7 at least
X,Y	US 4902745 (BAYER) see column 1, lines 30-52; column 3, line 25	X:1,8 and 9 at least Y:6 and 7 at least
X,Y	US 4845145 (EXXON) see Claim 1; column 3, lines 22-23	X: 1,8 and 9 at least Y:6 and 7 at least

X Document indicating lack of novelty or inventive step  
Y Document indicating lack of inventive step if combined with one or more other documents of same category.  
& Member of the same patent family

A Document indicating technological background and/or state of the art.  
P Document published on or after the declared priority date but before the filing date of this invention.  
E Patent document published on or after, but with priority date earlier than, the filing date of this application.



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Application No: GB 9706252.5  
Claims searched: 1-9

Examiner: K. Macdonald  
Date of search: 25 June 1997

Category	Identity of document and relevant passage	Relevant to claims
X	US 4664275 (TERUMO) see Claim 1	1 at least

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.